

THE BITTERSWEET STORY OF THE STEVIA HERB

The sweet stevia herb has had a long, safe history of use as a food and medicine in South America and Asia, but in many Western countries it is illegal as a food or food additive but legal as a dietary supplement.

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History and Chemistry

It's easy to grow, wonderful as a sweetener, contains medicinal properties, is non-caloric, safe to cook with, and has great potential in agriculture. It's widely used in South America and Asia. So why isn't stevia a household name in the rest of the world?

Stevia rebaudiana Bertoni is a herb native to Paraguay. It is also known as "honey yerba" and "honeyleaf" and by other variations of these names. The mature plant stands from around 65 centimetres (26 inches) to as tall as 180 cm (72 in) when cultivated or growing naturally in fertile soil. Historical records show that the leaves have been used for hundreds of years by the Guarani Indians, who named the plant *caá-êhê*. The main use was as a sweetener, particularly in their green tea, known as *maté*. It was also used in medicine or as a snack. Stevia's leaf is estimated to be 150 to 300 times sweeter than refined sugar.

M. S. Bertoni, in the late 1800s, was the first European to document stevia. In 1931, French chemists extracted stevioside from the herb in the form of an intensely sweet, white crystalline compound. The herb was then considered for use as a sweetener during the food shortages experienced by Britain during World War II. However, interest waned when sugar again became available.

Since this time, stevia has been used extensively in many Asian and South American countries, but the USA, Canada, Australia and Europe have not embraced the herb as a sweetener, opting either for sugar from readily available sugar cane or sugar beet, or for aspartame-based and other artificial sweeteners as a sugar substitute.

More than 150 varieties of stevia exist, but *Stevia rebaudiana Bertoni* is the only sweet stevia plant. Carbohydrate-based compounds from the stevia leaf can be isolated to glycosides known as *steviosides*. Stevioside is a glycoside of the diterpene derivative *steviol*, and is a natural component of the plant. Stevioside is intensely sweet and is present at levels up to 13% in the leaves of *Stevia rebaudiana Bertoni*. Rebaudiosides and dulcosides are other sweet chemical constituents of the plant that can be extracted.

Stevia, the FDA and Big Business

In the USA, stevia does not have "Generally Recognized As Safe" (GRAS) status for consumption, and is therefore "prohibited from use in human food" under the Dietary Supplement Health and Education Act (DSHEA) of 1994. According to the Act, any food or drink containing stevia is an "adulterated" substance. However, while stevia may not be sold as a sweetener, it may be legally purchased and taken internally. In amongst all the contradiction and confusion, this means that stevia is available for human consumption—but only when classified as a dietary supplement or herb.

It has been suggested that stevia has not been granted GRAS status in the interests of Big Business. In the late 1980s, a trade complaint was registered with the FDA, as tea containing stevioside was being sold by Celestial Seasonings. The Stevia.net website has a copy of an FDA memorandum concerning the incident; it was obtained through the Freedom of Information Act, and complainant names (company name and legal representatives) were deleted by the FDA to protect the informant's identity.

In 1991, stevia was deemed unsafe and was banned from the USA completely. It was only legalised as a dietary supplement due to the changing of law with the introduction of the DSHEA.

According to a 1994 article by Rob McCaleb of the Herb Research Foundation, the FDA began visiting businesses selling stevia around 1987, saying it was an unapproved food additive. One FDA inspector reportedly told a company president that the manufacturer of NutraSweet® had made complaints to the FDA to try to stop the use of stevia.

After the 1991 Import Alert banning the importation of stevia into the USA, the Herb Research Foundation produced a review by Doug Kinghorn, PhD, on behalf of the American Herbal Products Association (AHPA). The peer-reviewed work concluded that stevia was safe, based on scientific evidence and historical use. The AHPA then filed a petition with the FDA to have stevia leaf exempted from food additive regulations. However, the FDA concluded that there was insufficient evidence to prove stevia's safety. McCaleb asserts that evidence required to establish stevia as a food is far more comprehensive than that required for artificial sweeteners such as aspartame.

Julian Whitaker, MD, believes that the FDA "has been after stevia since 1986, coincidental with the growing popularity of aspartame".

GD Searle and Company developed aspartame (now commonly marketed as NutraSweet®) by accident when creating an ulcer drug. Many health complaints have been reported about the negative health effects of aspartame, from headaches to tumours.

According to James S. Turner, lawyer and co-founder of the Aspartame Consumer Safety Network, Searle funded 100% of the safety studies undertaken from 1985 to 1995 which found aspartame to be safe. Apparently all studies not funded by industry raised questions. Information linking tumours to aspartame was dismissed by the then FDA Deputy Commissioner, who went on to become Vice President of Clinical Research for Searle.

According to another report by health author Gail Davis, a similar situation occurred in 1983 when aspartame was approved for use in soft drinks. The FDA Commissioner left soon afterwards to become a consultant for Searle's public relations firm.

GD Searle was bought by Monsanto in 1985 and then acquired in 2000 by J.W. Childs Equity Partners II LP. The company asserts that more than 200 objective studies have found NutraSweet to be safe and that these papers were reviewed by relevant regulatory authorities such as the FDA, etc. Neotame is the new sweetener to be marketed by the company. It is 40 times sweeter than NutraSweet and 8,000 times sweeter than sugar. [For more on aspartame, see feature articles in NEXUS 2/28, 3/01, 7/04 and 7/05.]

Stevia's Safe Historical Use

Many foods have not had to go through the process of being approved for GRAS status. Through historical use, it is assumed they are safe for human consumption. Supporters of stevia have put this argument forward to the FDA, but without success.

Stevia.net contends that Celestial Seasonings was permitted to use stevia because the herb has had a long history of common use without adverse health effects. Furthermore, the 1991 Import Alert acknowledges stevia's use throughout history and is therefore an admission of its qualification as having GRAS status.

The American Herbal Products Association maintains that stevia is a food, as it has had a long history of food use, hence it should fall into the safe category.

Sunrider Corporation also tried this tack in 1995, stating that stevia was a "grandfathered" or "old" dietary ingredient, as it had been contained in their products before the DSHEA of 1994. However, this approach became problematic because the company had signed a consent decree in 1984 not to sell stevia, as "Sunrider decided it was not financially prudent to judicially contest this matter".

In 1998, the Stevita Company and the US FDA received considerable media attention after it was reported that the FDA had ordered the burning of books sold by Stevita.

The Stevita Book-burning Saga

In 1998, the Stevita Company and the US FDA received considerable media attention after it was reported that the FDA had ordered the burning of books sold by Stevita. These contained information on the herb along with stevia recipes.

The refuseandresist.org website reported in July 1998 that Stevita had endeavoured to import stevia in 1987 as "Stevia Sweet", but the FDA ordered the labels changed so as not to imply the substance would be used as a sweetener. Later on that year, FDA agents visited the company's warehouse and took copies of three books sold on stevia.

FDA Dallas then detained a shipment of stevia at customs in February 1998, the reason later given that the shipment was contaminated because of the previously released literature. A March 6 letter regarding this matter reportedly stated that the literature "rendered the product adulterated".

The FDA took inventory at Stevita in April and May 1998, and Oscar Rodes agreed not to sell the books, as the hold-up was affecting business. "We had already been forced to let employees go...we have to eat," he

said in the report. The FDA then arranged to come and take inventory, and stated in a fax that an investigator would "be available to witness the destruction of the cookbooks, literature and other publications". Rodes then notified the FDA agents on arrival that he would *not* destroy the books, but would videotape any actions by the FDA to do so.

Dr Julian Whitaker became involved when he had his attorney prepare a lawsuit to prevent destruction of the books. In his article on the subject, Whitaker makes a point about the power of the FDA by quoting from Tulane University professor James P. Carter's 1992 book, *Racketeering in Medicine: The Suppression of Alternatives*. Carter states: "The FDA serves as the pharmaceutical industry's watchdog, which can be called upon to attack and destroy a potential competitor under the guise of protecting the public."

The Aspartame Consumer Safety Network reported that in June 1998, James Kirkland—author of one of the banned books—attended a congressman's public meeting at which he

displayed two books. One, written by himself, was on cooking with stevia, and the other book gave information on constructing home-made bombs. He held up the books and asked the rhetorical question, "Which of these publications is legal?"

Whitaker contends that Patricia and Oscar Rodes of Stevita were given poor legal advice, which led to their agreeing to stop selling their books. He says that James Lahar from the FDA mandated a book-burning when he and other agents confiscated the company's stevia, pressuring Stevita not to sell the books. Oscar Rodes called his local television station to attract public attention to his company's plight. FDA officers initialled and dated six books so they could not be sold.

Whitaker reported that the FDA backed down after his lawyer filed suit, advising that no books would need to be destroyed and that Whitaker may buy any of the books himself.

The story according to the FDA is quite different. After the public's attention was gained, FDA documentation is clearly above the District Office level. In a memo to file on April 9, 1999, FDA Acting Associate Commissioner for Regulatory Affairs, Gary J. Dykstra, maintained that FDA never ordered the books destroyed. Nevertheless, he acknowledged that an FDA letter of May 19, 1998, states that "a current inventory must be taken by an investigator of this office, who will also be available to witness destruction of the cookbooks, literature, and other publications for the purpose of verifying compliance". The memo also notes that "Neither Stevita nor its attorney, Ms Sarracino, had informed FDA that the company intended to destroy these materials". However, he goes on to state that "the District Office assumed that the company might choose to destroy them".

An October 26, 1998, letter from Dan Burton, Chairman of the Committee on Government Reform and Oversight, 105th Congress of the US House of Representatives, stated that the FDA had no authority from Congress to be available to witness the destruction of books. Furthermore, it would be more appropriate under the First Amendment "to refuse to be a party to the destruction of the books". Burton adds that FDA's May 19 letter was "grossly inappropriate...(regardless of whether the company agreed to allow the agency to violate [sic] its First Amendment rights)".

Oscar Rodes denies he chose to destroy the books. As reported on refuseandresist.org, Rodes refuted the FDA claim by stating: "That's absurd. I don't want to destroy my own books! How would I ever recover the cost?"

FDA investigators also requested a copy of *The Stevia Story: A Tale of Incredible Sweetness and Intrigue*, by Linda Bonvie, Bill Bonvie and Donna Gates. This created a stir, as the book was published independently of Stevita, though it was available for sale through the company. Furthermore, the book questions FDA's treatment of stevia. Eventually, no action was taken regarding this item. As the FDA stated, "the book did not mention Stevita or its products and the agency had no interest in the book".

Books considered problematic by the FDA included *Cooking with Stevia*, by James Kirkland, and *The Natural Choice*, by Kay Randall (also known as Patricia Rodes). Both persons were involved in managing Stevita Company. Dallas District Office informed the firm's lawyers by telephone on

May 27, 1998, that "literature or publications that promote Stevita stevia products for use as a conventional food and that are marketed with or displayed with those products cause the products to be adulterated as an unapproved food additive".

The agency also noted in correspondence on June 8, 1998, regarding books, that "FDA had advised Mr Rodes that he should take care not to use them to stimulate sales of Stevita brand stevia, as that could cause them to be labeling [sic] under the Federal Food, Drug and Cosmetic Act".

Cooking with Stevia was the book that an FDA official dated and initialled so it could not be sold. This action was taken on six copies of the book. Whitaker's attorneys, Emord and Associates, noted the action in their letter of June 8, 1998, when they accused the FDA of acting unlawfully under the United States Constitution. After a mix-up over the amount of books defiled, Emord and Associates wrote that the "material point is not the number of books defiled, but that the agents defiled any of the books". Dan Burton's letter to the FDA makes a similar point, stating that "FDA has no authority from Congress to issue an enforcement letter that provides for the

use of FDA officers to take a 'current inventory' of a dietary supplement company's books..."

The FDA responded to claims of its acting inappropriately regarding the destruction of books by stating that it had "acted within its authority under the FD&C Act and the requirements of the First Amendment". However, FDA revised its Compliance Policy Guide "to provide further guidance regarding the disposition of books and other printed materials that serve as labeling".

This was due to the petition submitted on behalf of Julian M. Whitaker and also David Dean Richard, an author of one of the books called into question. Richard stated in an affidavit that he lost sales of his book due to the FDA's actions of June 1998. Under FDA guidelines, labelling can include "a book, reference publication, or a reprint or copy of a scientific journal article".

Whether or not FDA maintains its position and stevia remains illegal as a food or food additive, it is still available as a food supplement, therefore the end result is the same: humans ingest it, anyway.

Chairman of the Committee on Government Reform and Oversight, Dan Burton, noted this inconsistency in his letter to the FDA: "I find the agency's treatment of stevia baffling (it is safe as a dietary supplement but unsafe as a food additive?)..."

Stevia Safety Studies

Various concerns have been expressed over the safety of stevia. Many countries have claimed their reason for not considering stevia for consumption is the lack of conclusive proof of its safety.

In a Joint FAO/WHO Expert Committee on Food Additives (JECFA) report on stevioside, it is noted that in rats, stevioside "is not readily absorbed from the upper intestine but is hydrolysed to the aglycone, steviol, before absorption from the gut." The effects of steviol on the body are not completely known, but it may be a problem because animal studies are contradictory. It was found that steviol: "...exhibited greater acute toxicity than stevioside in hamsters but not in rats. Steviol was clearly genotoxic [DNA damaging] after metabolic activation,

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inducing forward mutations in bacteria and gene mutations and chromosomal aberrations in lung fibroblasts of Chinese hamsters." This may sound frightening, but the amount given to animals during testing of such substances can be up to 1,500 times any daily amount relative to body weight that a human would ingest.

The Committee also noted that the material tested "was poorly specified or of variable quality", not necessarily representative of the commercial product, and that "no studies of metabolism of stevioside and steviol in humans were available". Due to these considerations, the Committee concluded that it could not give stevia an Acceptable Daily Intake (ADI) rating.

The Scientific Committee on Food (SCF) for the European Commission, in its "Opinion on Stevioside as a Sweetener" adopted on June 19, 1999, came to the conclusion that, "of the specific stevioside preparation for which approval is sought", "the substance is not acceptable as a sweetener on the presently available data". Its position was similar to that of JECFA, including its concerns due to "questionable chronic toxicity and carcinogenicity studies, and possible effects on the male reproductive system that could affect fertility".

The study most commonly referred to when raising contraceptive concerns over stevia was undertaken in 1968, Professor Joseph Kuc of Purdue University, Indiana, being the principal researcher. Stevia.net reports that the study was carried out on rats, after it had been alleged that South American women used the herb for contraception. Kuc acknowledges that the findings may not be applicable to humans, but believes his methods were sound. The website quotes from *The Stevia Story* (Bonvie, Bonvie and Gates) and states that the rats in the study were given very high concentrations of stevia—and "...material from the stevia plant that would not ordinarily be consumed. This liquid replaced the animals' drinking water, and was given at such a rate as to equate with a person drinking 2.5 quarts [approximately 2.8 L] of liquid in less than half

an hour". Agriculture and Agri-Food Canada reported that further "studies conducted to confirm this result have all been negative".

The Lipton petition, an application to the FDA to use stevia in its products, is also quoted, making the point that "if this reproductive effect in rats is real and can be extrapolated to humans, then one might suspect that there would be very few children in some regions of Paraguay".

Two separate Thai studies have found that reproduction in rats and hamsters is not affected by stevia. A study published

in 1991, from Chulalongkorn University Primate Research Centre in Bangkok, found that "stevioside at a dose as high as 2.5g/kg body wt/day affects neither growth nor reproduction in hamsters". Chiang Mai University researchers had work published in 2000 regarding a study of rats being fed aqueous extracts of stevia and other plants. The findings stated that "all the investigated plant extracts have no toxic effect on male rat reproduction and progeny outcome".

However, a University of São Paulo, Brazil, study published in 1999 came up with different findings when "chronic administration" of stevia showed that "Stevia extracts may decrease the fertility of male rats".

Lack of detailed studies seems to be a problem where stevia safety is concerned. The SCF's "Opinion on *Stevia rebaudiana Bertoni* plants and leaves", adopted on 17 June 1999, evaluates the herb as a novel food and concludes that "no appropriate data were presented to enable the safety of the commercial plant product to be evaluated"—perhaps because the applicant just didn't supply enough information. SCF also notes that there was "no satisfactory data to support the safe use of these products as ingredients of food or as sucrose substitute for diabetics and obese individuals".

Professor Mauro Alvarez's work was referenced in the SCF's opinion and has been used by the FDA to raise doubt regarding the safety of stevia. Alvarez takes exception to his work being used out of context, particularly by the FDA in the past.

A letter expressing his frustration is posted at Stevia.net, where he states, "I can assure that our conclusions in these various studies indicate that Stevia is safe for human consumption as per intended usage, that is, as a sweetener".

A common argument put forward by stevia supporters regarding the safety of stevia is that it has widespread usage in South America and many Asian countries including China, Korea and Japan.

A Success Record in Asia

Stevia is widely used throughout the Asian region. It has been considered safe for use in food for many years. In fact, the situation is quite the reverse of that in the USA, Canada, Europe and Australia. Many artificial sweeteners such as aspartame are illegal in Asian countries because of safety concerns. Companies using substances like aspartame in the USA, etc., are using stevia in Asia.

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Genetically Modified Food



STRAIGHT BANANA



HOLELESS DONUT



TEFLON SPINACH (won't stick to teeth)

S.

In Japan, companies like Sunkist and Nestlé use stevia as a sweetener. Coca-Cola uses stevia in Japan for its Diet Coke, as the herb is non-caloric. A combined Australian university/government report states that "Japan is by far the most advanced country in the use and understanding of Stevia in its application in the food and pharmaceutical industries". At present, the stevia industry in Japan is endeavouring to obtain Codex Alimentarius approval of steviosides. Interestingly, there have been no unfavourable health reports regarding stevia in Japan in the past 30 years.

China has been using stevia since 1985. Shanghai City's Director of the Health Supervisory Institute was quoted in the *Shanghai Star* as saying, "over the past 17 years there hasn't been any documented case of the sweetener causing ill effects".

Stevia's Positive Health Effects

Studies have found some positive effects and possible medical uses of stevia. A University of Illinois, College of Dentistry paper, published in 1992, found that stevioside, though an intense natural sweetener, is not cariogenic, according to their data. A Japanese study from Nihon University, published in late 2002, revealed that the use of stevioside on skin tumours in mice inhibited the promoting effect of chemically induced inflammation.

Taiwanese studies showed the possibility of stevia's use for blood pressure regulation. A study undertaken on rats at Taipei Medical University, and published in 2002, showed that stevioside lowered blood pressure. The other study, published in 2000, was undertaken on humans by Taipei Medical College and concluded that "oral stevioside is a well-tolerated and effective modality that may be considered as an alternative or supplementary therapy for patients with hypertension".

Two recent studies by Jeppesen et al., from Aarhus University Hospital in Denmark, have found after tests on rats and mice that stevioside could have potential in the treatment of type-2 diabetes.

Natural therapists have been using stevia for many years to regulate blood sugar levels. According to a June 28, 2002, report on Australia's national broadcaster ABC (<http://www.abc.net.au>), the herb can be taken in droplet form with meals, bringing blood glucose levels to "near normal".

Users of stevia have also reported lower incidence of colds and flu. The herb can aid in weight loss by reducing appetite and can be used to suppress tobacco and alcohol cravings. Stevia leaf also contains various vitamins and minerals including vitamins A and C, zinc, rutin, magnesium and iron.

Stevia has been used in South America for years as a treatment for diabetes. It has also been suggested that it can aid people to get off insulin. It has been used topically on skin cancers and to treat candidiasis.

The Healthfree.com website also espouses stevia's use for skin care. It can be applied to enhance the skin's appearance or to heal acne and other blemishes and skin disorders including dermatitis, eczema and seborrhoea. The website also

reports that stevia can be used to heal cuts and scratches quickly and without scarring.

Brian Morley is a natural therapist with a biochemistry background, working in Brisbane, Australia. Morley uses stevia on patients as he says it "assists the liver in controlling blood sugar levels in the body". He says that refined sugar has a negative effect on the liver and can cause chronic fatigue and immune deficiency syndrome. Combined with bilberry, stevia can also aid sugar cravings. Morley uses stevia in a "nectar form" that has been vacuum distilled, nitrogen dried and crystallised so as not to destroy any goodness.

Stevia's Uses in Food Preparation

Stevioside is suitable for cooking purposes as it is heat stable, unlike artificial sweeteners such as aspartame. However, it is unsuitable for certain confectionary such as fudge or icing as it lacks bulk.

Stevia is used in Japan to sweeten soy sauce, pickles and soft drinks. Brazil almost followed suit in 1988 when the Minister for Health proposed that only stevia should be allowed for sweetening diet drinks.

However, Big Business opposed the idea, according to a report in *Earth Island Journal* (Northern Winter 1997-98 issue). Apparently Monsanto had made a substantial financial commitment in the construction of a NutraSweet plant in São

Paulo. It was then agreed that manufacturers would undertake studies by 1989 to incorporate stevia. However, nothing further was heard regarding the matter.

Stevia's Potential in Agriculture and Healthcare

One of the advantages of stevia is that it can be grown almost anywhere. Its native conditions are subtropical, but it has been grown in areas as far north as St Petersburg (60°N). The herb also grows well in tropical areas.

Stevia seedlings can be purchased from nurseries. The plant has the added bonus of having certain insecticidal properties; for example, it is aphid resistant.

Agriculture and Agri-Food Canada notes that "Stevia represents a new opportunity for researchers and farmers alike", but that more information is required to "optimize annual transplant production for Canada".

Stevia could be utilised to benefit research, as "production of remarkably high levels of one class of secondary metabolite is of significant interest for chemists, biochemists and geneticists and may prove to be a foundation for the production of new metabolites in the future". It also noted that because of safety concerns surrounding stevia, "there is clear need for further experimentation with respect to the metabolic fate of steviol glycosides".

Stevioside is not legal in Canada, and the only legal way of obtaining stevia is by purchasing it as a herb. In Australia and New Zealand, the situation according to Food Standards Australia New Zealand (FSANZ) is that stevia leaf may be sold as a food. However, extractable components of the plant, such as stevioside, are not legal.

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The Rural Industries Research and Development Corporation (RIRDC) was set up by the Australian government "to work closely with Australian rural industries on the organisation and funding of their R&D needs". Professor David Midmore and Andrew Rank put together a report for RIRDC in 2002 on the possibility of "A new rural industry—Stevia—to replace imported chemical sweeteners". The study was jointly funded by RIRDC and Central Queensland University.

The report refers to Canadian researchers' findings that 50 hectares of stevia could produce sweetener equivalent to one million dollars' worth of sugar. This "in Australia would require 240 hectares of cane to grow, i.e., productivity in terms of sweetness equivalent per hectare is high". It notes it will be necessary to "develop production and processing practices that result in acceptable financial returns to growers" yet a competitively priced end-product.

Environmental considerations are also positive in regard to stevia as an industry in a dry continent like Australia. Primary producers could benefit because the crop would offer "greater diversification opportunity and returns per megalitre of irrigation water". Insects do not appear to be of concern to stevia. There are some possible diseases "which do not appear to be a major problem", according to the report, and "spraying for control is sometimes undertaken".

David Midmore says that Australia is ready for stevia. "The time is right for large-scale production, provided we can ensure that production practices are suitable (e.g., mechanical harvesting) and that it will be grown in the correct locations (weather-wise)."

According to the report, it is expected that "consumer demand for natural sweeteners will escalate" as Australians become more health conscious and as "the incidence of dia-

betes in Australia and abroad" grows. It is also suggested that stevia could be marketed "in conjunction with sugar" to produce low-calorie products.

However, input from other organisations and agencies will be required to ascertain if "the constraints to production and acceptance of steviosides will be manageable in the near (2-3-year) future".

Currently there is an application with FSANZ for consideration of stevia as a sweetener, and according to Professor Midmore a decision "should be announced by FSANZ in a short while". A possible obstacle to the FSANZ acceptance of stevia could be the same concern expressed by JECFA: that

the breakdown of stevioside into steviol can exhibit some toxic and mutagenic activity. However, David Midmore stresses that "such breakdown is not known to happen *in situ* in the human body".

A Sweet Future for Stevia

Stevia has had a long history of use as a natural sweetener and a medicinal aid. It is heat stable, non-caloric and can be used by diabetics.

However, the US FDA has had a questionable relationship with the herb, and issues have been raised

over the safety of the stevioside extract. Yet, no adverse health effects have ever been reported or documented, including in Asia where the herb is used extensively as a sweetener.

Stevia shows great potential for the future, in agriculture and as a food.

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The report refers to Canadian researchers' findings that 50 hectares of stevia could produce sweetener equivalent to one million dollars' worth of sugar.

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